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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,677	05/31/2002	Joerg Schneider	620-190	4825

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EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,677	SCHNEIDER ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-21* is/are pending in the application.

4a) Of the above claim(s) *9 and 14-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-13 and 17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3-21-02 + 3-22-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on 1-18-2006 is acknowledged. Claim 10 has been amended claims 17-21 have been added.

Election/Restrictions

Applicant's election with traverse of Group III in the reply filed on 1-18-2006 is acknowledged. The traversal is on the ground(s) that all three of the groups outlined in the restriction requirement are drawn to "heterologous prime-boost" which is not disclosed by Kazanji et al. This is not found persuasive because as pointed out by Applicant, Kazanji et al. disclose the administration of naked DNA plasmids containing the HTLV-I-*env* gene as the "primer" and the administration of Ad5 containing the HTLV-I-*env gp46* gene as the "booster". Since the genes administered in the "primer" and the "booster" are different and the form of said compositions are different (i.e. naked DNA plasmid vs. Ad5 viral vector), said compositions are deemed to be heterologous to one another. Consequently, the special technical feature to which Applicant refers does not constitute a contribution over the prior art. Hence, there is no unity.

The requirement is still deemed proper and is therefore made FINAL.

Claims 9-21 are pending. Claims 9 and 14-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 10-13 and 17-21 are currently under examination.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because:

> Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Specification

The use of the trademark Biojector has been noted in this application (see page 12 for example). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claims 10-13 and 17-21 are objected to because of the following informalities: Claim 10 recites limitations drawn to non-elected inventions. The elected invention is drawn to methods of inducing a CD8+ T cell immune response comprising administering a priming composition comprising a nucleic acid encoding an antigen and boosting composition comprising an adenovirus vector. Claim 10 includes language drawn to non-nucleic acid priming compositions. Claims 11-13 and 17-21 are included in the objection as they depend from claim 10. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-11 and 18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/686,943. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are drawn to methods of generating a CD8+ T cell immune response utilizing priming and boosting compositions comprising viral vectors wherein said vectors contain DNA encoding T cell epitopes of a given antigen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-13 and 17-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is rendered vague and indefinite by the use of the phrase "nucleic acid encoding said antigen or epitope operably linked to regulatory sequences for the production of said antigen or epitope in the individual by expression from the nucleic acid". It is unclear what is meant by said term. How can "expression" link regulatory sequences to a nucleic acid? Moreover, it is unclear what the phrase "expression from the nucleic acid" means. Consequently, it is impossible to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-13 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over McMichael et al. (WO 98/56919) and Kazanji et al. (International Journal of Cancer, 1997, Vol. 71, pages 300-307 -- IDS filed on 3-21-2002).

McMichael et al. disclose methods of inducing a CD8 T cell immune response comprising the administration of a priming composition and a boosting composition wherein said boosting composition comprises a non-replicating or replication impaired pox virus vector (see abstract). Moreover, McMichael et al. further disclose the priming composition can comprise a nucleic acid (either DNA or RNA) that is packaged or in free form (see page 11, lines 4-8), Ty-VLP or a recombinant adenovirus (see page 12, lines 4-5). McMichael et al. further disclose that the MVA can be used (see page 12, lines 6-9) in both the priming and boosting compositions (see page 13, line 29-30) and that a variety of viral vectors (including herpes virus) can be used in the priming composition (see page 13, lines 7-16).

McMichael et al. differs from the instant invention in that they do not explicitly disclose the use of boosting compositions comprising non-replicating or replication impaired adenovirus vectors.

Kazanji et al. disclose the administration of naked DNA plasmids containing the HTLV-I-*env* gene as the "primer" and the administration of Ad5 containing the HTLV-I-*env gp46* gene as the "booster" (see abstract). Moreover, Kazanji et al. disclose that adenovirus vectors have the

potential for oral immunization, are cheaply produced and have been successfully used in vaccines against EBV (see page 300. left hand column).

Consequently it would have been obvious for one of ordinary skill in the art at the time the invention was made to use the adenovirus vectors disclosed by Kazanji et al. in the compositions and methods disclosed by McMichael et al. in order to take advantage of the ability of the adenovirus vectors to be orally administered and to be cheaply made.

One would have had a reasonable expectation of success as adenovirus vectors have been successfully used in other vaccine compositions and in prime-boost methodologies (see Kazanji et al.).

Claims 10-13 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over McMichael et al. (WO 98/56919) and Natuk et al., 1993, AIDS Research and Human Retroviruses, Vol. 9 No. 5, pages 395-404 -- IDS filed on 3-21-2002).

McMichael et al. disclose methods of inducing a CD8 T cell immune response comprising the administration of a priming composition and a boosting composition wherein said boosting composition comprises a non-replicating or replication impaired pox virus vector (see abstract). Moreover, McMichael et al. further disclose the priming composition can comprise a nucleic acid (either DNA or RNA) that is packaged or in free form (see page 11, lines 4-8), Ty-VLP or a recombinant adenovirus (see page 12, lines 4-5). McMichael et al. further disclose that the MVA can be used (see page 12, lines 6-9) in both the priming and boosting compositions

(see page 13, line 29-30) and that a variety of viral vectors (including herpes virus) can be used in the priming composition (see page 13, lines 7-16).

McMichael et al. differs from the instant invention in that they do not explicitly disclose the use of boosting compositions comprising non-replicating or replication impaired adenovirus vectors.

Natuk et al. disclose the use of vaccines comprising recombinant adenoviral vectors in prime-boost protocols (see abstract). Natuk et al. further disclose that human adenoviruses possess significant advantages as vectors for recombinant vaccines including a strong safety record and multiple serotypes that can be exploited as vectors for booster immunizations (see pages 395 right hand column to page 396 left hand column).

Consequently it would have been obvious for one of ordinary skill in the art at the time the invention was made to use the adenovirus vectors disclosed by Natuk et al. in the compositions and methods disclosed by McMichael et al. in order to take advantage of the safety and versatility associated with adenovirus vectors.

One would have had a reasonable expectation of success as adenovirus vectors have been successfully used in vaccines for the prevention of acute respiratory disease (see page 396 in Natuk et al.).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ROBERT ZEMAN
PATENT EXAMINER

March 16, 2006